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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/224,781	01/04/1999	BARRY M. LIBIN	1059-007	3261

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EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/224,781

Applicant(s)

LIBIN, BARRY M.

Examiner

Frederick F. Krass

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Election of Species Requirement

Applicant's election (August 11, 2004) of "*Candida albicans*" and "cetylpyridinium chloride" as ultimate species of fungus and cationic antimicrobial agent, respectively, for prosecution on the merits is acknowledged.

Claim Informalities

The following amendments are suggested to place the claims in better form:

Claims 27, 29 and 30, the third line of each claim, in each instance immediately after "cationic" there should be inserted --- antimicrobial agent ---.

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23 and 26, second and third lines of each claim, in each instance "the affected disease sites" lacks antecedent basis.

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Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 23, 24 and 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Libin (USP 5,236,699).

Patentee discloses using mouthrinses comprising a combination of triclosan and cetylpyridinium chloride to inhibit plaque formation and treat periodontitis (col. 4, lines 57-60).

The instant preamble "of treating fungal infections" is viewed as non-limiting since it does not recite essential steps "necessary to give life, meaning and vitality" to the claimed subject matter. Pitney Bowes, 51 USPQ2d at 1165-66; Kropa v. Robie, 88 USPQ 478, 480-81 (CCPA 1951). The body of the claim following the preamble is a self-contained description of the method (contacting "affected disease sites" with triclosan) and does not depend on the preamble for completeness. Furthermore, no particular "affected disease sites" are specified; the gums of the prior art patients are "affected" with the disease periodontitis. The amount of triclosan used by the prior art to treat periodontitis is substantially the same as that used by Applicant to treat fungal infections, and thus also meets the instant limitation that an amount "effective to alleviate the symptoms" of a fungal infection be used.

2) Claims 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 670 711 B1.

The prior art discloses the treatment of fungal infections, including oral *Candida*, with a combination of triclosan and nisin. The reference makes clear that both compounds are acting as

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antifungal agents: see paragraph [0009]. The compositions may be in mouthwash (liquid) or gel (semi-solid) form. See paragraph [0015]. See also working examples 1, 4, 6, 9, 10, 13 and 25.

3) Claims 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 2 160 099 A.

The prior art discloses the use of triclosan, either in solution with alcohol or water, or in an ointment (see page 1, lines 35-38), to treat athlete's foot fungus.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 23-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Libin (USP 5,236,699) in view of EP 0 670 711 B1.

The primary reference is discussed in subsection "1)" of the "Anticipation" section above and discloses using mouthrinses comprising a combination of triclosan and cetylpyridinium chloride to inhibit plaque formation and treat periodontitis (col. 4, lines 57-60). For the purposes of completeness of prosecution and for this ground of rejection only, the presumption will be made

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that the instant claims do in fact positively recite the treatment of fungal infections. (See the related discussion in subsection "1)" of the "Anticipation" section above). Accordingly, for the purposes of this rejection the prior art differs from the instant claims because it is silent regarding the treatment of fungal infections.

It is known that both triclosan and cetylpyridinium are active against the oral fungus *Candida*. See the secondary reference, especially at working example 25, spanning pages 13 and 14. The reference also recognizes that these agents are equally useful in inhibiting plaque. See paragraph [0043].

It would have been obvious to have administered mouthrinses comprising triclosan and cetylpyridinium chloride to patients having oral *Candida*, motivated by the desire to simultaneously inhibit plaque as taught by the primary reference, and to treat the *Candida* fungus as taught by the secondary reference.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 10:30AM- 7PM;
Tuesday: 10:30AM - 7PM;
Wednesday: off;
Thursday: 10:30AM- 7PM; and
Friday: 10:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system,

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see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
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A handwritten signature in black ink, appearing to read 'Fred Krass', is written below the printed name and title.